



1624 5 NOV 16 P2:26
F & A DAIRY of CALIFORNIA, INC.

Division of Docket Management,

We would appreciate your time in looking into the matter of starter growth media becoming exempt from the labeling of allergens. The information in this packet is a collage of correspondence and scientific study of allergens, in particular, soy. Our question is, do we have to declare soy as an ingredient because of the starter growth media? What seems to be a simple question has turned out to be not so simple. I have spoke with Steve Taylor, the technical director for the University of Nebraska. My understanding was that the end product, which is our finished cheese, will not test positive for soy proteins; however that does not mean they do not exist, but because of the process, they are harmless, denatured. A test to prove this does not really exist. Where does that leave us? I sent an e-mail to FDA asking this question and the reply was that FDA has not determined if growth media used to make enzymes are considered part of an ingredient under the Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA). Upon reading the Guidance for Industry: Question and Answers, question number 1 states: Under FALCPA, a "major food allergen" is an ingredient that is one of the following five foods or from one of the following three food groups or is an ingredient that contains protein derived from one of the following:

Milk, egg, fish, crustacean shellfish, tree nuts, wheat, peanuts, soybeans.

If FDA has not determined if our media is an ingredient, do we fall under the FALCPA guidelines and declare soy? Thank-you for your time.

Debbie Barry

Quality Control Manager
F&A Dairy of California, Inc.

FALN 003

2005FL-0488

FLN 1

691 Inyo Street
Post Office Box 578
Newman, California 95360

209/862-1732
In California: 800/554-6455
Out of State: 800/626-6580
FAX: 209/862-1043

IMAC

PRESENTS A PROVEN SUCCESS

ELIMINATE INTERNALTM

(A PATENTED PRODUCT)

**INGREDIENTS: SWEET WHEY, SOY & MILK HYDROLYZATES
(STIMULANT), CALCIUM-PHOSPHATE BUFFERS, AUTOLYZED
YEAST EXTRACT, NON FAT DRY MILK, DEXTROSE AND
ALL OTHER MINOR STIMULANTS AND MINERALS (<1.5%)**

WEIGHT: 60 LBS.

05178R

®D

**INTERNATIONAL MEDIA AND CULTURES
2550 LARIMER ST. DENVER, CO 80205
TELE: 303-292-3939 FAX: 303-292-4615**

Mergis



International Media And Cultures

10/17/2005

Ms. Debbie Barry (Q.A. Manager)
F & A Dairy
691 Inyo Street
Newman, CA 95360

Dear Ms. Barry,

IMAC has prepared the supporting evidence to show F.D.A., that IMAC starter media with hydrolyzed soy solids is non-allergenic on the basis of thermal, enzymatic, and acid hydrolysis treatments during media ingredient preparation, starter making, fermentation, and cheese making and aging. We have also prepared the statistical data to show concrete evidence that over 600,000,000 pounds of cheese made (prior to January 2006) in U.S. and it was consumed by over 500,000,000 people (two times the total U.S. population) without any complaints from consumers, health department, U.S.D.A. or F.D.A. Also, U.S.D.A., F.D.A. and other governmental agencies have inspected the media, checked the cheese made with it for allergens and came up with negative results. We have also obtained medical professional opinions to indicate that the cheese made with IMAC starter media with soy solids as an ingredient is non allergenic. The IMAC media with hydrolyzed solids have been in use in the U.S. for the past 5 years (prior to January 2006) and did not call for declaration of soy solids in the cheese cultures on finished cheese labels as per 21 C.F.R. (code of Federal Regulations) of the U.S. Food and Drug Administration and as per the director of F.D.A. and U.S.D.A. personnel.

Since the new law is being introduced with regard to allergens, following the guide lines of food allergen labeling and consumer protection act of 2004 (title II of public law 108-282, dated August 2, 2004), IMAC was ready to submit to Food and Drug Administration a notification to grant exempt status (page No. 3, subsection 7, title II of public law 108-282), under food allergen labeling and consumer protection act of 2004, from labeling on the finished cheese and other dairy products, the hydrolyzed soy solids as an ingredient of the cheese starter cultures. We have asked you to obtain the correct address and the appropriate F.D.A. office to send this notification. When you send a communication to F.D.A., on behalf of IMAC, requesting where to send this notification, surprisingly, their reply indicated that starter media at this stage is not considered by F.D.A. as a part of the ingredient under the food allergen labeling and consumer protection act of 2004 (FALCPA). Consequently, it is not necessary to send this notification for exempt status by neither cheese manufacturers (F&A Dairy) nor

culture media manufacturer (IMAC) because, it is already exempted, according to the agency.

The reply you have received from F.D.A., on October 7th, 2005, answers the question, "should we declare soy solids as part of the starter media ingredients on the finished cheese label? Apparently, according to Ms. Graciela M. Iguina of U.S. Food and Drug Administration, under the subject reference: allergen labeling-starter (growth) media, F.D.A. has not determined if growth media used to make starter cultures are considered part of an ingredient under the food allergen labeling and consumer protection act of 2004 (FALCPA). It is the interpretation of our legal and professional counsel of the F.D.A. response of October 7th, 2005, that the hydrolyzed soy solids, and/or soy solids used in the starter medium does not have to be declared on the cheese label as part of the cheese starter cultures, since F.D.A. has not determined if growth media used to make starters are considered part of ingredient under 2004 FALCPA. Consequently, the labeling on the finished cheese does not change and FALCPA does not apply to starter media and/or cultures, according to F.D.A. judgment and interpretation.

You have asked the following question to F.D.A. on October 6th, 2005: "we are a cheese manufacturer. Our starter media base is of hydrolyzed soy. We have tests to prove that there is no allergen in our product after processing. The question is, do we need to declare soy and if so, where can I send our research in order to prove no allergen exists? Thank you for your time. The following reply came from F.D.A.: regretfully, at this time we cannot provide an answer to your e-mail. F.D.A. has not determined if growth media used to make enzyme (starter culture) are considered part of an ingredient under the food allergen labeling and consumer protection act of 2004 (FALCPA). According to our counsel, it goes to prove that you do not have to declare soy along with cheese cultures on your finished cheese label. Consequently, you do not have to submit your research to F.D.A. Considering this, either you the cheese manufacturer or IMAC (starter media and culture producer) do not have to send supporting evidence to F.D.A. However, I recommend holding the data, along with the e-mails from F.D.A., addressed by Ms. Graciela M. Iguina, at the plant, under your possession, to show any governmental agencies, if they question.

Ms. Iguina of F.D.A. has also mentioned in her communication that you may wish to review the guidance for industry. It is clearly stated as follows in the guidance for industry, under the section, "questions and answers regarding food allergens, including the food allergen labeling and consumer protection act of 2004", final guidance, that FALCPA (the food allergen labeling and consumer protection act of 2004) does not require any action with respect to product labeled before January 1st, 2006. This answer is in response to the following question No. 3, "must products with labels that do not comply with "FALCPA" are removed from the market place once the new labeling law is effective? Since you have been using IMAC starter media with soy solids as stimulants for the past five years with no allergy complaints, and F.D.A. and U.S.D.A. are aware of this fact (because you are a U.S.D.A. inspected plant), according to F.D.A.'s (answer to

question No. #3) guidance for industry, you do not have to worry about changing any labels. It (FALCPA) only applies to those who are starting to use such products for the first time (without history or evidence from manufacturer) after January 1, 2006, that too if they do not have sufficient scientific evidence or statistical data to prove it is not an allergen or if it is not in compliance with FALCPA's guidelines. Under question No. 16, it is stated clearly that any advisory statement such as "may contain (allergen)" must be truthful and not misleading. Also, F.D.A. advised that advisory labeling such as "may contain (allergen)" should not be used as a substitute for adherence to current good manufacturing practices (CGMP). None of these things apply to you because according to the communication you have received from F.D.A., it states that F.D.A. has not determined if growth media used to make enzymes (starters) are considered part of an ingredient under the food allergen labeling and consumer protection act of 2004. In other words, 2004 FALCPA does not apply to IMAC starter media, with hydrolyzed soy solids as an ingredient, to be used in the cheese manufacture. To safe guard yourself, you may request all other suppliers irrespective of what they are supplying to give you an affirmative statement stating that their ingredients are free from allergens, if there is no major allergen declaration on their label. It will protect you in the long run. Under the new law, you may have to reject products which uses vague words such as may contain an allergen, unless the supplier gives you substantial evidence to show it is free from an allergen, if the allergen is not declared on their label. It must be specific, to safe guard your company.

Answer to question No. 17, clearly states currently F.D.A. has no threshold levels for allergens and F.D.A. at some point need to consider a threshold level for one or more food allergens in the context of reviewing a petition or a notification submitted to request that an ingredient be exempt from FALCPA's labeling requirements. It does not pertain to your use of IMAC's starter media with hydrolyzed soy solids as stimulants in your cheese, because F.D.A. has not determined if growth media used to make enzymes (starters) are considered part of an ingredient under the food allergen labeling and consumer protection act of 2004 (FALCPA). Consequently, it does not pertain to you at all. Also, answer to question No. 3, under guidance for industry, published on October 5th, 2005, clearly states that FALCPA does not require any action with respect to products labeled before January 1, 2006. Accordingly, you are totally exempt from any label changes.

Considering your communication with F.D.A. and their reply to your direct question, regarding allergen labeling, assures the fact that you or for that matter any body who use IMAC media with soy solids as stimulants, do not have to change the label on the finished cheese.

For the past few years, IMAC has been in touch with F.D.A. and U.S.D.A, regarding this matter. All along they told us the same thing i.e. starter media and cultures have a different status than other ingredients. Consequently they have allowed the industry without declaring the soy solids in the cultures on the finished cheese ingredient declaration. Now, it is finally in writing from F.D.A.,

and hence it is our firm understanding that you do not have to declare anything in the cultures, on the finished cheese label. You did an outstanding job of confronting F.D.A. on this issue. If they had any concerns, they could have objected it. Since they did not object, here after, there is no necessity for changing the ingredient declaration on the cheese label, as clearly outlined in guidance for industry, questions and answers regarding food allergens, including the food allergen labeling and consumer protection act of 2004, final guidance, published on October 5, 2005, by the U.S. Food and Drug Administration and the communication you have received from F.D.A. on October 7th, 2005.

Yours Sincerely,


M.S. Reddy, Ph.D.

Cc:

V.R. Mantha, Director of Research-IMAC
Ed Price, General Manager-IMAC, Orchard
Alvin Thompson, Plant Manager-IMAC, Sabetha
Adam Rose, Culture Plant Manager-IMAC Denver
U.S. government agencies and pertinent personnel
Pat Dowdle-IMAC, Attorney

Attachments shown as exhibits:

1. Request to F.D.A. on October 6, 2005
2. Reply from F.D.A. on October 7th, 2005
3. Food allergen labeling and consumer protection act of 2004 (title II of public law 108-282), published on August 2, 2004.
4. F.D.A.'s guidance for industry, regarding 2004 FALCPA, published on October 5th, 2005
5. Communication on exempt status for starter growth media.